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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/976,472	10/11/2001	John F. Sims	2932-B	9942

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EXAMINER	
ANDRES, JANET L.	

ART UNIT	PAPER NUMBER
1646	11

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,472	SIMS ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 11 is acknowledged. The restriction requirement of paper no. 9 is made FINAL. Non-elected claims 11-23 are cancelled by Applicant's amendment and claims 1-10 are therefore pending and under examination in this office action.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide a utility for the claimed invention (see below). The priority date granted is therefore the filing date of the instant application, October 11, 2001.

Specification

3. The disclosure is objected to because of the following informalities: There are sequences on p. 13, lines 25-26 and 28-29, and on p. 39 that lack sequence identifiers. See MPEP §2422

Appropriate correction is required.

The use of the trademarks FLAG, RNEASY, ABI PRISM, TAQMAN, COSTAR, and DELFIA have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1- 10 are rejected under 35 U.S.C. 101 because the claimed invention lacks a substantial, specific, or well-established utility.

Claims 1-10 are drawn to polynucleotides that encode an interleukin-1-like polypeptide. The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

A utility such as chromosome localization, set forth by Applicant on p. 27, would apply to virtually every naturally occurring polynucleotide and is therefore not specific. While Applicant has mapped the sequence to a particular region of chromosome 2 and states that it could be used to identify abnormalities associated with this region, Applicant has not identified any conditions known to be associated with rearrangement or deletion of the polynucleotide. Applicant further states on pp. 27-28 that the polynucleotide could be used to develop treatments for disorders resulting from defective or insufficient expression of the gene corresponding to the polynucleotide, or to inhibit gene expression. However, the specification does not disclose any

diseases or conditions that are known to be associated with the encoded protein. Further, there is no actual biological activity disclosed for the protein and no teachings to indicate that it even exists; all that is presented in Figure 3 is message expression. Thus, further research is required to identify what diseases, if any, could be beneficially affected by altering levels of the encoded polypeptide.

Applicant further states on pp. 28-30 that the encoded polypeptide could be used to identify binding molecules and to deliver drugs to such molecules, and on p. 31 that it could be used to study biological actions resulting from such binding. Such studies are useful only in research to determine the function of the protein itself: there is no "specific benefit in currently available form" to be derived from identifying a molecule that binds to a protein of unknown function. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. See also the Revised Interim Utility Guidelines available at www.uspto.gov.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The specification indicates that the disclosed polynucleotide encodes an interleukin-1 like molecule and is "likely to be involved in" the same functions (p. 31). Applicant states that the invention could thus be used to study IL-1 mediated processes, to protect against infection, and to stimulate the immune system, and that inhibitors of the encoded polypeptide could be used as anti-inflammatory agents (p. 32). However, members of the interleukin-1 family have diverse functions. IL-1α and IL-1β are pro-

inflammatory, but IL-1Ra, which is also a member of the interleukin-1 family, is an inhibitor of inflammation (see for example, EP 0879889, Young et al., 1998, p. 2. lines 1-32). IL-18, also known as IFN-γ inducing factor, is also a member of this family but has distinct effects: unlike IL-1α and IL-1β it does not cause fever (Dinarello, 1998, Annals NY Acad. Sci. Vol. 856, pp. 1-11, see pp. 1 and 6). Members of the interleukin-1 family thus have distinct functions; identifying a polynucleotide as a member of this family does not endow it with a specific and substantial utility.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 1, 4, 7, and 10 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for polynucleotides encoding the polypeptide of SEQ ID NO: 2 and means of expressing them, would still not reasonably provide enablement for polynucletides encoding variants or fragments of the polypeptide. The claims encompass polynucleotides encoding polypeptides of 80% homology to the disclosed sequence, as well as

polynucleotides encoding fragments. As stated above, there is no activity disclosed for the encoded polypeptide. Applicant has thus not described the properties or characteristics are required for a functional protein. Since the biological activity of the parent polypeptide is not defined in the specification, it is unpredictable as to which variants, if any, would be have the same characteristics as the parent polypeptide. Thus one of skill in the art would not be able to make polynucleotides encoding polypeptides with such characteristic features; they are not described in the specification. Therefore, without further guidance from the specification as to the required structural and functional characteristics of polynucleotides encoding IL-1eta proteins, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

9. Claims 1, 4, 7, and 10 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to a genus, i.e. polynucleotides encoding fragments and variants of SEQ ID NO: 2 and means of expression. Applicant has disclosed one species, the polynucleotide encoding the polypeptide of SEQ ID NO: 2, but has not disclosed sufficient species for the broad genus of 80% homologues and fragments that bind to receptors.

Since claims are drawn to polynucleotides encoding homologue and fragments, they encompass polynucleotides that vary substantially in length and also in composition. The disclosure of a single species of polynucleotide thus does not adequately describe the scope of the claimed genus. The instant specification fails to provide sufficient descriptive information,

such as definitive structural or functional features of the claimed genus. There is no description of the conserved regions which are critical to the structure and function of the genus claimed; as stated above, no activity is disclosed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from other interleukin-1 family members are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed: there is no guidance in the art as to what the defining characteristics of IL-1 eta might be. Thus, no identifying characteristics or properties of the instant polynucleotides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NO: 1 and the encoded polypeptide of SEQ ID NO: 2 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 4, 7, and 10 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by WO 01/40291, Burgess et al., June 7, 2001.

Burgess et al. teaches a sequence, SEQ ID NO: 9, figure 12A, that encodes a protein that is identical to amino acids 9-157 of instant SEQ ID NO: 2 and is 95% homologous overall (see sequence alignment attached to document). This sequence thus anticipates the limitations of instant claim 1(c) and, since it would hybridize under moderately stringent conditions, of claim 1(e). Expression vectors, as claimed in claim 4, host cells, as claimed in claim 7, and means of expression, as claimed in claim 10, are taught on pp. 41-45.

12. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al., J. Biol. Chem., 2000, vol. 275, no. 2, pp. 1169-1175.

Smith et al. teaches a sequence identical to instant SEQ ID NO: 1 (see attached sequence from GenBank). Vectors, host cells, and expression are taught on p. 1170, column 2.

13. Claims 1, 4, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 5,945,310, Young et al., 1999, and European patent application EP 0 879 889 A2, Young et al., 1998.

The '310 patent teaches SEQ ID NO: 1, which encodes a polypeptide whose first 88 amino acids are identical to instant SEQ ID NO: 2 (see attached alignment). The polynucleotide would hybridize to complements of SEQ ID NO: 1 under moderately stringent conditions, anticipating the limitations of claim 1(e). Vectors, host cells, and means of expression are taught

in column 10, lines 56-67, and column 11, lines 1-60, thus anticipating the limitations of claims 4, 7, and 10.

EP 0 879 889 A2 teaches the same sequence as the '310 patent in SEQ ID NO: 1, thus similarly anticipating the limitations of claim 1(e). Vectors, host cells, and means of expression are taught on p. 9, lines 40-58, and p. 10, lines 1-21, anticipating the limitations of claims 4, 7, and 10.

14. Claims 1, 4, 7, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patent application 2002/0068279 A1 (Burgess et al., priority date Dec. 6, 1999).

This application teaches SEQ ID NO: 9, figure 12A, which is the same sequence taught by WO 01/41291 (see sequence alignment attached to document) and thus similarly anticipates the limitations of claim 1(c) and 1(e). Expression vectors, host cells, and means of expression are taught on p. 16-18, paragraphs 164-180, anticipating the limitations of claims 4, 7, and 10.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

Patent Examiner
February 24, 2003